Italian government should block self-replicating mRNA drugs

THE RISK OF THE SPREAD OF SELF-REPLICATING mRNAs

- On 12 December 2024, the EMA's "Committee for Medical Products for Human Use" (CHMP) approved the release of a marketing authorization for the medicinal product Kostaive;
- On 12 February 2025, the European Commission, implementing the EMA's indication, granted the authorization to market "Kostaive".

What does Kostaive consist of

It is a pharmaceutical product based on artificial lipid vesicles containing mRNA molecules encoding the Spike protein of SARS-CoV-2 designed to induce protective immunity against COVID-19. However, unlike the pharmaceutical products by Pfizer/BioNTech and Moderna, the mRNA molecules included in Kostaive **are self-replicating molecules.** Once inside the cell, these molecules trigger the production of the Spike protein and **can replicate themselves indefinitely** (Fig. 1).

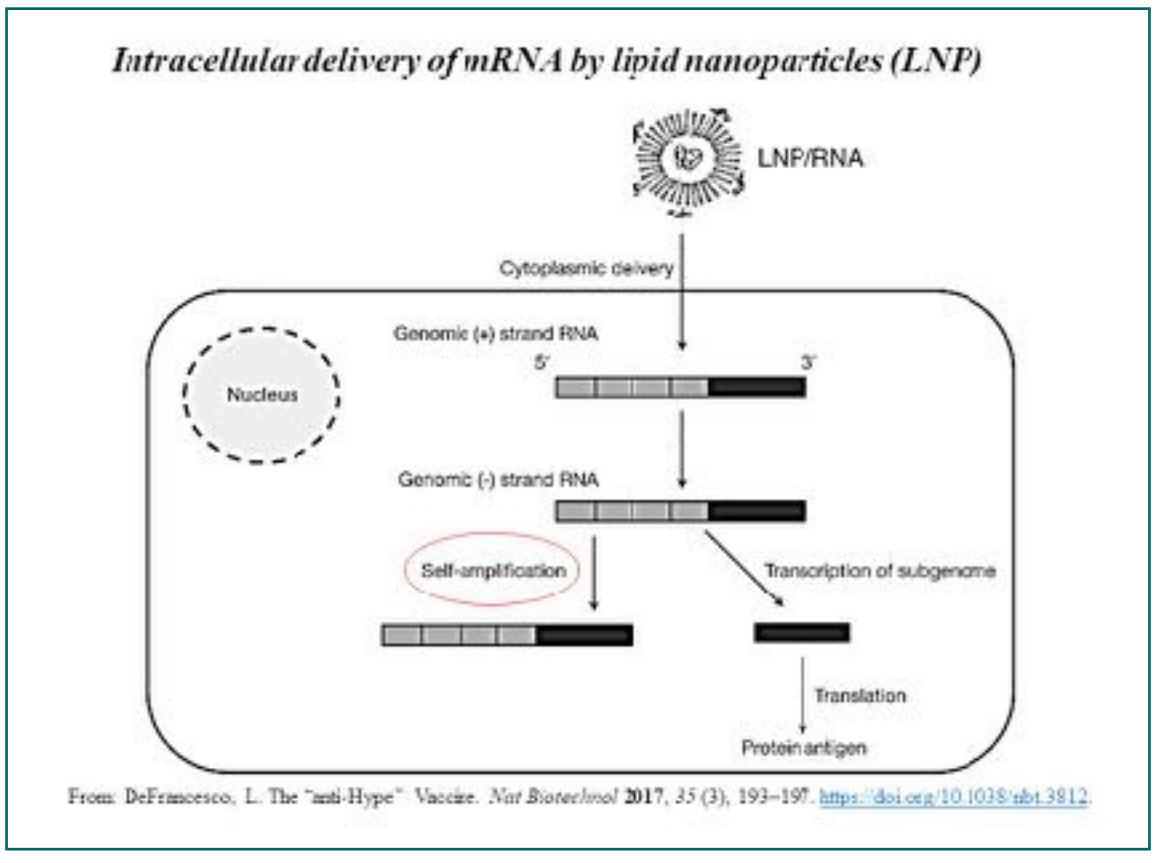

Fig. 1. Schematic representation of the immunogen production mechanism based on the self-amplifying mRNA such as Kostaive.

Current scientific knowledge suggests that the intracellular accumulation of self-replicating mRNA may prompt the cell to activate basic self-defense mechanisms, encapsulating the mRNA into nanovesicles such as exosomes and extracellular vesicles, which are then released into the intercellular space.

Consequently, these nanovesicles incorporating the self-replicating mRNA can circulate throughout the body spreading in other tissues, including the respiratory one.

In fact, as was shown in the study by Bansal and co-authors [ref: https://doi.org/10.4049/jimmunol.2100637], a similar mechanism can occur with the secretion of exosomes containing the vaccine-derived Spike protein (Pfizer/BioNTech), which were detected in blood from two weeks up to four months after vaccination.

Due to their nature, such nanovesicles can potentially enter any cell of the inoculated organism and, through the respiratory tract or the exchange of biological fluids, **spread to other organisms without any species barrier.** Therefore, based on current theoretical knowledge, nanovesicles containing self-replicating mRNA will be potentially able to spread among humans as well as animals of any species.
Based on these assumptions, **an accurate evaluation of the enormous biological risk associated with this technology appears extremely urgent**. This is regardless of any assessment of the questionable added value of using Kostaive compared to current anti-COVID-19 vaccines.

We ask for accurate tests to verify that the transmission mechanism, possible on a theoretical basis, does not occur in the body, so as to avoid the errors of negligence committed with the indiscriminate administration of genetic vaccines against COVID-19.

To give just one example, millions of pregnant women have been inoculated with mRNA pharmaceuticals products, excluding a priori the potential transmission of the vaccine's genetic material to the fetus. However, the study by Chen and co-authors [ref: https://doi.org/10.1016/j.omtn.2025.102489] has recently shown that **mRNA-1273 (Moderna) is placenta-permeable and immunogenic in the fetus.** Why was this study only carried out after millions of pregnant women had been inoculated with these pharmaceutical products, without giving them the chance for a truly informed consent?

We invite the Regulatory Authorities to show due caution.

In fact, it has already been scientifically demonstrated that exosomes not only circulate throughout the body, transporting their molecular cargo from one tissue and organ to another, but can also reach the lungs and be exhaled outside [ref.: https://pubmed.ncbi.nlm.nih.gov/38988301/ - https://pubmed. ncbi.nlm.nih.gov/23683467/ - https://pmc.ncbi.nlm.nih.gov/articles/PMC11043690/]. **The release of self-replicating RNA into the environment involves very specific risks for humans, other animals and possibly also plants and the environment as a whole,** which have already been clearly outlined in the scientific literature [ref.: https://enveurope.springeropen.com/articles/10. 1186/s12302-024-00966-x] and which **must be scrupulously evaluated in the case of this new product.**

About Us

The **independent Medical-Scientific Commission (CMSi)**,

- Prof. Marco Cosentino, Pharmacology and Toxicology, PhD
- Dr. Maurizio Federico, PhD in Biology
- Dr. Panagis Polykretis, PhD in Structural Biology
- Dr. Alberto Donzelli, expert in Public Health, specialist in Hygiene and Preventive Medicine
- Dr. Patrizia Gentilini, specialist in Oncology ed Ematology
- Prof. Eduardo Missoni, Global Health, Develop. and Manag.mnt of Int.l Orgs, MSc, specialist in Tropical Medicine
- Dr. Sandro Sanvenero, Doctor of Dental Science
- Dr. Eugenio Serravalle, specialista in Pediatrics

With endorsements from:

- *Dr. Paolo Bellavite, specialist in Clinical and laboratory Ematology and independent researcher*
- *Prof. Mariano Bizzarri, Sperimental Med., Director Systems Biology Lab. Un. La Sapienza, PhD*
- *Prof. Giovanni Frajese, professor of Endocrinology and Dysmetabolic Diseases*
- *Dr. Dario Giacomini, specialist in Radiology*
- *Dr. Laura Teodori, former Research Director and Professor of Biological Risk, PhD*
- *Prof. Stefano Petti, PhD. Top 2% world scientists (ranking Univ. Stanford)*

What we ask

1. **Appropriate preclinical and clinical safety evaluation of all products based on RNA/LNP biotechnology platforms**
2. **Moratorium on mRNA Autoreplicating drugs**
3. **Intervention by the Italian Government at the European Commission and the EMA**

Bibliography

https://doi.org/10.4049/jimmunol.2100637
https://doi.org/10.1016/j.omtn.2025.102489
https://pubmed.ncbi.nlm.nih.gov/38988301/
https://pubmed.ncbi.nlm.nih.gov/23683467/
https://pmc.ncbi.nlm.nih.gov/articles/PMC11043690/
https://enveurope.springeropen.com/articles/10.1186/s12302-024-00966-x